

EXHIBIT 37

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION OPIATE)
LITIGATION)

This document relates to:)

) MDL No. 2804

The County of Summit, Ohio, et al. v. Purdue)
Pharma L.P., et al., Case No. 18-op-45090)

) Hon. Dan Aaron Polster

The County of Cuyahoga, Ohio, et al. v. Purdue)
Pharma L.P., et al., Case No. 17-op-45004)

Expert Report of Larry Holifield

May 31, 2019

I. INTRODUCTION

My name is Larry Holifield. I am the co-founder and Director of Corporate Integrity Services LLC, located at 5846 S Flamingo Road #3170, Cooper City, Florida. I have been retained as an independent expert witness by counsel for McKesson Corporation in In Re National Prescription Opiate Litigation, Case No. 17-md-2804, before the U.S. District Court for the Northern District of Ohio.

I understand that McKesson Corporation and other defendants in the above-referenced litigation may use my expert testimony at trial.

I prepared this report to comply with Rule 26(a)(2) of the Federal Rules of Civil Procedure. This report summarizes my current opinions, which are subject to change depending on ongoing discovery and additional information. My opinions in this report are based upon my training, education, and experience, as well as my review of documents in this case (as identified in Appendix B). My opinions set forth in this report are stated to a reasonable degree of certainty.

For trial, I may prepare visual aids to demonstrate various aspects of my testimony.

II. QUALIFICATIONS AND COMPENSATION

I have 37 years of combined law enforcement experience.

From 1970 to 1984, I worked for the St. Louis Police Department (“SLPD”). Throughout my career with the SLPD, I attended training programs to maintain my certification as a police officer in the State of Missouri. I also earned a Bachelor of Arts Degree in Political Science and Legal Justice in 1977 from Maryville University of St. Louis while working with the SLPD.

During my time as a police officer, I worked in a variety of different assignments, including uniform patrol and vice squad until being promoted to narcotics detective in 1976, which I remained throughout my tenure in the department. I received numerous awards at SLPD including Chiefs’ Letters of Commendation. I left the SLPD in 1984.

In 1984, I began working for the United States Drug Enforcement Administration (“DEA”). I worked for DEA for 23 years (1984-2007).

During my time at DEA, I served in multiple senior management roles, overseeing the investigation of international drug rings as well as supervising several units that focused on investigating drug diversion.

With tours of duty in Guatemala, Colombia, Mexico, and El Paso, Texas, I spent a significant portion of my DEA career investigating drug trafficking into the United States from Central America, South America, Mexico, and along the Southwest Border. In those roles, I developed expertise on international drug cartels and the flow of illicit drugs across the Southwest Border; I negotiated directly with law enforcement (including Justice Department officials) and numerous government agencies in foreign countries to reform their drug laws; and

I became familiar with the statutes and regulations that DEA relies on to combat drug trafficking and diversion.

From 1987 to 1992, I was a special agent assigned to the Guatemala City Country Office, which covered El Salvador, Belize, and Guatemala. During this timeframe, our office focused on combatting the emergence of new drug trafficking routes through Central America. Colombian drug trafficking organizations had opened these new routes in response to increased law enforcement efforts concentrated on the preexisting routes through the Southeastern United States and the Caribbean.

From 1992 to 1994, I was the Group Supervisor of the Organized Crime Drug Enforcement Task Force ("OCDETF") and reported to the Assistant Special Agent in Charge of DEA's San Francisco Field Office. As the Group Supervisor of OCDETF, I led the investigation of long-term, complex criminal cases. The majority of those cases involved multi-jurisdictional conspiracies of 20-30 people, and almost all had a nexus with Mexico or Colombia. We investigated drug cartels trafficking in crack cocaine, heroin, and methamphetamines. In 1994, I opened the DEA's Oakland, California Office, which also targeted major drug trafficking organizations primarily from Mexico and Colombia.

In 1996, I received a special assignment as liaison to the Central Intelligence Agency in Bogota. Then, in 1998, I received a temporary promotion to become the Assistant Country Attaché to Bogota, Colombia.

In 1999, I returned to DEA Headquarters, at which time my promotion became permanent. I was assigned to be Co-Chair of the Linear Committee, a multi-agency task force that investigates large transnational narcotics traffickers. Although I was familiar with suspicious activity reports ("SARs") used to identify financial links to the illicit drug trade from my prior duties as a Special Agent, I became more familiar with the complex statutes and regulations that mandate SARs by financial institutions during this tour of duty. In this role, I also attained significant knowledge regarding international drug cartels and the illicit sources of drugs abused in the United States.

In 2000, I became Section Chief for Mexico and Central America.

Later in the year 2000, I was transferred to Assistant Special Agent in Charge of the El Paso Field Office. During my time in the El Paso Field Office (2000-2002), I supervised all DEA units operating out of the office, including a diversion unit that consisted of diversion investigators and special agents. As part of my duties, I was responsible for conducting criminal investigations and enforcing compliance with the Controlled Substances Act and its implementing regulations.

From 2002-2006, I was the DEA's Regional Director for Mexico and Central America. During that time, I oversaw two diversion investigators and was involved in high-level meetings and discussions with the Mexican government about drug-related reforms. At the time, my work on drug reform in Mexico was critical to combatting drug abuse in the United States because Mexican laws relating to the sale of drugs like pseudoephedrine had a direct impact on the availability of that substance to the drug cartels that used it to manufacture the methamphetamine

they trafficked across the border. I also continued to interface with and rely upon agents who had special training in suspicious activity reports (“SARs”) to identify financial links to the illicit drug trade.

From 2006-2007, I served as the Deputy Special Agent in Charge of the DEA’s Miami Field Division and was responsible for all DEA personnel in Florida from the top of the state down to Miami. DEA had a large Diversion Group in Florida at the time and its supervisor reported to me on its activities on a weekly basis. The Diversion Group had personnel in the Miami office and in regional offices in Ft. Lauderdale, Jacksonville, Orlando, and Tampa. In 2006-2007, the Diversion Group was focusing on investigations into internet pharmacies and pill mills, but it also worked with the State of Florida to reform Florida’s loose laws concerning licenses to own and operate pharmacies.

In 2007, I retired from the DEA. Throughout my career at DEA, I regularly attended training seminars and courses, including, but not limited to, asset forfeiture training, fingerprinting training, and training provided by CIA related to my international duties. I also received numerous awards while at DEA, including Sustained Superior Service Awards, two DEA Administrator’s Awards, and the Warren Medal from CIA.

In 2008, I began working for TurnStone Investigative Group as a Regional Director in Miami, Florida. At TurnStone, I managed and conducted complex domestic and international investigations. I am licensed as a private investigator in the state of Florida.

In 2012, I co-founded Corporate Integrity Services LLC (“CIS”), which is a licensed private investigative agency that provides consulting and investigative solutions to corporate entities, law firms, and individuals. From 2012 to present, I have worked as the Director of CIS. As part of my work at CIS, I frequently advise Mexican and other foreign clients about compliance with US drug laws, including DEA regulations.

My resume is attached as Appendix C.

I am being compensated for my time at my standard rate of \$250 per hour. My compensation is not based on the outcome of the litigation.

III. SCOPE OF REPORT

I have been asked to offer opinions on the following topics.

- 1) DEA’s operational structure and its enforcement priorities as they relate to the investigation of illicit drugs and the diversion of legal medications.
- 2) Registrants’ statutory and regulatory obligations related to maintenance of effective controls and controlled substance transaction reporting, including DEA’s enforcement of those requirements prior to the Distributor Initiative.
- 3) The evolution of diversion trends in the United States in the mid-2000s, including the role that rogue internet pharmacies played in that rise, and the resulting efforts

by DEA's Office of Diversion Control to adapt its existing regulations to address these new threats.

- 4) The options available to enhance DEA's regulatory and enforcement efforts to address new trends in diversion.
- 5) The effect of additional suspicious order reporting on DEA's efforts to prevent diversion.
- 6) The contributors to the abuse of illicit drugs and legally produced controlled substances that are outside the control of registrants.

IV. SUMMARY OF OPINIONS

- A. DEA has historically prioritized combating illicit drugs and the transnational and domestic criminal organizations who traffic them over combating diversion of prescription drugs.
 1. DEA's priorities are evidenced by the personnel it assigns to each task, the organizational structure it has adopted, and the resources it devotes to each task.
 - a) DEA often assigns diversion investigators without law enforcement powers to investigate diversion of prescription drugs, and assigns DEA agents with law enforcement powers to investigate illicit drugs and related criminal organizations.
 - b) DEA is organized so that diversion investigators ultimately report through their chain of command to DEA special agents.
 - c) DEA devotes greater resources and attention to investigate illicit drugs and related criminal organizations than it assigns to investigate diversion of prescription drugs.
 2. This prioritization reflects DEA's focus on illicit drugs and related criminal organizations as a more harmful factor in the existing drug crisis than the diversion of prescription drugs.
- B. The Controlled Substance Act ("CSA") and DEA's implementing regulations set forth limited—and sometimes vague—requirements related to registrants' responsibility to maintain effective controls against theft or diversion.
 1. The purpose of CSA and DEA's implementing regulations is to keep prescription drugs safe within the "closed system of distribution."
 2. The DEA's implementing regulations have largely remained the same since 1971.

3. The standards for determining whether registrants are maintaining effective controls against theft and diversion are contained in 21 C.F.R. §§ 1301.71-1301.76.
 - a) The regulations state that the determination of whether a registrant has provided “effective controls against diversion” are based upon compliance with “the standards for physical security controls and operating procedures necessary to prevent diversion” as set forth in 21 C.F.R. §§ 1301.72-1301.76, e.g., defining the required thickness of the concrete surrounding a controlled substance vault, requiring restricted access to controlled substance processing areas, etc.
 - b) The only due diligence of a customer that a registrant is required to conduct under the regulations is a “good faith” effort to ensure the customer is registered to possess controlled substances. The regulations do not state that a registrant must conduct any other investigation of its customers.
 - c) The only requirements related to “suspicious orders” under the regulations is that a registrant must implement a system to identify and report “suspicious orders” to DEA.
 - d) The regulations do not state that a registrant must investigate “suspicious orders” or halt them prior to shipment.
 4. My opinions regarding the CSA and DEA’s implementing regulations are consistent with my experiences supervising diversion units. The units’ inspected pharmacies to ensure they were secured against theft and had accounted for their inventory of controlled substances. The units also reviewed registrants’ suspicious order monitoring programs for compliance.
- C. New diversion trends in the mid-2000s demonstrated the inadequacy of the existing DEA regulations; DEA responded by attempting to stretch the 1971 regulations to address the new problem.
1. The unprecedented rise of rogue internet pharmacies, and later pills mills, were the primary diversion threat in the mid- and late-2000s.
 2. DEA was under significant pressure to address the rise of prescription drug abuse in the mid-2000s.
 3. In response, DEA sent a “Dear Registrant” letter in December 2007 that attempted to change the expectations set forth in DEA’s regulations.

4. Through these letters, and without support in the CSA or its implementing regulations, DEA attempted to shift its law enforcement role to registrants who did not have at their disposal the law enforcement experience or the many investigatory tools available to DEA, such as administrative subpoenas, search warrants, wire taps, undercover personnel to conduct surveillance, or the ability to seize records and computers.
- D. There were other legitimate options available to enhance DEA's regulatory and enforcement efforts to address new trends in diversion that were not implemented.
1. The CSA was not amended to expand the duties of registrants beyond those set forth in the original statute.
 2. DEA did not issue any new regulations or revise existing regulations relating to the control of the manufacture, distribution, and dispensing of controlled substances as it is authorized to do under 21 U.S.C. § 821.
 3. DEA did not provide specific guidance regarding how to identify "suspicious orders," investigate "suspicious orders," investigate their customers, and/or determine which "suspicious orders" or customers should be rejected.
- E. If registrants had filed more suspicious order reports it would not have had meaningful impact on DEA's efforts to prevent diversion.
1. DEA already had information on potential "suspicious orders" in its ARCOS data that it could use to identify possible diversion.
 - a) Distributors and manufacturers reported all transactions involving purchase or sale of prescription opioid medications to the ARCOS reporting system. ARCOS reporting tools allowed DEA to identify pharmacies that were receiving extraordinarily large volumes of narcotics; DEA did not need registrant's suspicious order reports to do that.
 - b) DEA did not provide registrants access to ARCOS data. Registrants only gained access to limited ARCOS data in 2018.
 2. Only a small fraction of suspicious order reports ever resulted in DEA actions against registrants, and DEA's regular practice was to not respond to the suspicious order reports received.
 3. There is no basis to conclude that additional suspicious order reports would have resulted in a meaningful decrease in diversion.
- F. Factors outside the control of registrants have contributed to the abuse of illicit drugs and legally produced controlled substances inside Summit County and Cuyahoga County.